REMARKS

Claims 1, 2, 5, 6, 9, 12 and 14 having been amended, claims 3, 4, 18-23 and 25-32 having been canceled, claims 33-44 having been added, the pending claims in the above-identified application are claims 1, 2, 5-17, 24, and 33-44. The Title of the Application has been amended per the Examiner's suggestion. The description of Figure 1 in the Brief Description of the Drawings has been amended to clarify that the Figure is on three sheets. The description of Figure 2 in the Brief Description of the Drawings has been deleted.

Reconsideration and withdrawal of the objection and rejections are respectfully requested.

Information Disclosure Statement

The Examiner has requested a copy of the references cited in the 1449 mailed by Applicants on May 22, 2003. A copy of the aforementioned references, as well as a copy of the corresponding International Search Report, is provided herewith.

Objection to the Claims

The Examiner objected to claims 1-17 and 24 as reciting non-elected SEQ ID NOs. Claims 3 and have been canceled and claim 1, 2, 5, 6, 12 and 14 have been amended to recite only elected SEQ ID NO:2. Thus, claims 1-17, 24 and 33-44 are all directed towards SEQ ID NO:2. Accordingly, withdrawal of the objection is respectfully requested.

Rejection Under 35 U.S.C. §101

The Examiner rejected claims 1-17 and 24 under 35 U.S.C. §101 as allegedly not being supported by either a specific and substantial credible utility or a well established one. Specifically, the Examiner states of page 6 of the Office Action that "[t]he claimed nucleic acid can't be used to diagnose any disorder, because instant specification does not establish a link between the claimed nucleic acid and any disorder. For example, is there a reduction or over-production of said claimed nucleic acid or the encoded polypeptide, relative to control tissue?". This rejection is respectfully traversed.

Applicants do not understand this rejection. Applicants maintain, however, that after reading the specification one of skill in the art would immediately appreciate the usefulness of the claimed invention. In support of a patentable utility, Applicants have submitted a Declaration under 37 C.F.R. §132 by Dr. Janine Bilsborough. The instant application discloses, for example, at page 55, lines 7-19, and at page 62, line 6, that zcytor17 plays a role in inducing inflammation by immune response cells.

Paragraph 8 of the Declaration shows that zcytor17 is expressed in human monocyte cell lines U937 and THP1 as determined by polymerase chain reaction ("PCR") and Northern Blot. Notably, zcytor17 expression is upregulated in monocytes when THP1 cells are grown in media which includes human interferon-gamma ("hIFNγ"), a well-known proinflammatory cytokine produced, for example, by activated CD4+ T cells (paragraph 9 of the Declaration). Paragraph 10 of the Declaration shows that zcytor17 mRNA levels are substantially upregulated in activated CD4+ and CD8+ T cells, as compared to resting CD4+ and CD8+ T cells. Thus, Applicants submit that zcytor17 expression is upregulated during an immune-mediated inflammatory response.

Paragraph 11 of the Declaration shows that BaF3 cells transfected with full-length zcytor17 (SEQ ID NO:2 as recited in pending claims 1, 2, 5-17, 24, and 33-44) and Oncostatin M receptor-beta (OSMR), and grown in activated CD3+ selected human cell conditioned media revealed a factor in the media that proliferated the BaF3/zcytor17/OSMR cells. The factor was discovered to be a novel four-helix bundle cytokine, zcytor17 ligand. See Examples 1-5 of U.S. Patent Application Serial No. 10/351,157, filed January 21, 2003, a copy of which was mailed to the Examiner on May 22, 2003 and whose consideration was noted in paragraph 4b of the Office Action dated August 26, 2003. Thus, as zcytor17 expression is upregulated in activated monocytes, CD4+ T cells and CD8+ T cells, and its cognate ligand promotes cellular proliferation, one of skill in the art would clearly recognize that zcytor17 is a involved in an immune-mediated inflammatory response. Importantly, a soluble zcytor17 receptor was able to diminish the proliferative response induced by zcytor17lig in the BaF3 experiment.

Paragraphs 14 and 15 of the Declaration show further evidence that zcytor17 has a physiological significant, real-world use. Zcytor17 expression is

upregulated in the involved tissue samples from patients diagnosed with inflammatory bowel disease ("IBD") and psoriasis. Thus, zcytor17 expression is upregulated in affected IBD and psoriatic tissue.

Alternatively, the Examiner has provided no evidence or scientific basis to refute the assertions of utility for the polypeptides of the present invention. The invention indeed has a specific asserted and a well-established utility for the claimed polypeptides that are supported by the specification. Thus, Applicants submit that the Examiner has not established a *prima facie* showing of lack of utility, because it has not provided sound scientific reasoning to rebut the assertion of utility in the application and the evidence presented by Applicants therein. In view of the Examiner's apparent failure to note and evaluate this evidence, Applicants submit that a *prima facie* showing of no specific and substantial credible utility has not been made.

For the above reasons, Applicants respectfully submit that the invention recited in claims 1-17 and 24 (claims 1, 2, 5-17, 24, and 33-44 as amended) is useful. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 are respectfully requested.

Rejection Under 35 U.S.C. §112

The Examiner rejected claims 1-17 and 24 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner stated on page 7 of the Office Action that the "[i]nstant specification does not define the physiological role of the zcytor17 polypeptide encoded by the claimed nucleic acid, neither does it establish a link between the claimed nucleic acid or the encoded protein and a physiological condition." This rejection is respectfully traversed.

As discussed above, Applicants have indeed asserted a specific and well established utility for the inventions recited in claims 1-17 and 24 (claims 1, 2, 5-17, 24, and 33-44 as amended). Applicants submit that claims 1-17 and 24 (claims 1, 2, 5-17, 24, and 33-44 as amended) are supported by a specific utility that is substantial and credible. Moreover, upon reading the specification, one of skill in the art would know

how to make and use the proteins of the present invention without undue experimentation.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-17 and 24 (claims 1, 2, 5-17, 24, and 33-44 as amended) under 35 U.S.C. §112, first paragraph, are respectfully requested.

Conclusion

In light of the above amendments and remarks, withdrawal of the objection and rejections is respectfully requested. It is, thus, respectfully requested that claims claims 1, 2, 5-17, 24, and 33-44 are in condition for allowance and notification to that effect is respectfully requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6540.

Respectfully Submitted,

Brian J. Walsh
Registration No. 45,543
Direct Dial - (206) 442-6540

Enclosures:

- Declaration under 37 C.F.R. §132
- Petition and Fee for Extension of Time (in duplicate)
- Amendment Fee Transmittal (in duplicate)
- 12 References
- Copy of corresponding International Search Report
- Postcard